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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/194,396 12/08/98 HOLGERSSON

J 45115-53906

000466 HM12/1116
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EXAMINER

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

11/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/194,396

Applicant(s)

Holgersson et al.

Examiner

Gerald Ewoldt

Group Art Unit

1644

☒ Responsive to communication(s) filed on Sep 11, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-6, 8, and 10-20 is/are pending in the application.

Of the above, claim(s) 15-19 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6, 8, 10-14, and 20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's request for a rejoinder of restricted Groups I-II, in Paper No. 9, filed 9/11/00, is denied. As unity of invention practice, and not U.S. restriction practice, applies to cases filed under 35 U.S.C. 371, Applicant is reminded that unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. The allowed combinations do not include multiple products as claimed in the instant application, see MPEP § 1850.

Claims 1-6, 8, 10-14, and 20 are being acted upon.

2. In view of Applicant's amendment and response, filed 9/11/00, only the rejections remain.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6, 8, 10-14, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in Paper No. 7, mailed 4/11/00. Note that this rejection was previously made to Claims 9-14 only. However, independent Claim 1, on which all claims under examination depend, has been amended to include the indefinite limitations previously limited to Claims 9-14.

Applicant's arguments, filed 9/11/00, have been fully considered but have not been found convincing. Applicant argues that the term "immunoglobulin properties" has been "given a reasonably precise definition in the specification." However, the disclosed passage (page 5, line 26 - page 6, line 7) provides no definition. Said passage merely discloses the source of said properties, i.e., that said properties are conferred by IgG. Said passage is silent as to a definition of said properties.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-6, 8, and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al. (1990) and U.S. Patent No 5,434,131 (1995) and Sako et al. (1993), all of record, for the reasons set forth in Paper No.7.

Applicant's arguments, filed 9/11/00, have been fully considered but have not been found convincing. Applicant argues that the instant invention comprises a product which is overexpressed and contains additional antibody binding sites compared to the product of the prior art, i.e., the instant product has superior activity to the product of the prior art. As evidence of superior activity Applicant has submitted an abstract (Liu et al., 2000) in which it is asserted that a PSGL-1/mIgG_{2b} fusion protein binds more pig endothelial cell cytotoxic antibodies from human serum than either pig thyroglobulin or Gal α 1,3Gal linked to glass beads. However, Applicant offers insufficient evidence that the instant product specifically binds more anti-Gal α 1,3Gal antibodies than the fusion protein of the *combined* prior art nor has Applicant provided sufficient evidence that said binding would be unexpected. The Liu et al. reference merely asserts that "PSGL-1/mIgG_{2b} is a very effective absorber of anti-pig antibodies".

Applicant further asserts that the fusion protein of the instant claims is about 100 times more active than the protein of the Tsuji et al. reference. Applicant is reminded that the claims were rejected over the *combined* Tsuji et al., U.S. Patent No 5,434,131, and Sako et al. references, and that assertions of superior activity lend no patentable weight in the absence of side-by-side comparison data and evidence of unexpected results. The Liu et al. abstract contains no side-by-side comparison data nor evidence of unexpected results when compared to the fusion protein of the combined references.

Applicant further argues a lack of motivation to combine the references. In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or

modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the addition of IgFc tags to fusion proteins for purification purposes, or the substitution of one well known Gal α 1,3Gal source for another, would not have taken "extraordinary inventive skill" for the reasons set forth in the previous Office action.

7. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al. (1990) and U.S. Patent No 5,434,131 (1995) and Sako et al. (1993) as applied to claims 1-6, 8, and 10-11 above, and further in view of Goding (1983), all of record, for the reasons set forth in Paper No.7.

Applicant's arguments, filed 9/11/00, have been fully considered but have not been found convincing. Applicant argues that the claims should be allowable in light of the arguments made for the allowability of Claim 1. However, Claim 1 has not been found to be allowable for the reasons set forth, supra.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al. (1990) and U.S. Patent No 5,434,131 (1995) and Sako et al. (1993) as applied to claims 1-6, 8, and 10-11 above, in view of Kozlowski et al. (1997) all of record, for the reasons set forth in Paper No.7.

Applicant's arguments, filed 9/11/00, have been fully considered but have not been found convincing. Applicant argues that the claim should be allowable in light of the arguments made for the allowability of Claim 1. However, Claim 1 has not been found to be allowable for the reasons set forth, supra.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

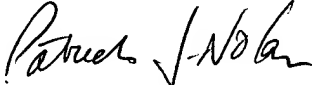
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
November 8, 2000


Patrick J. Nolan, Ph.D.
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